

App. No. 10/501,291
Office Action Dated January 4, 2007

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REMARKS

Reconsideration is respectfully requested in view of the above amendments and following remarks. Claims 1, 6, 9, 11, 28 and 30 have been amended. The limitation in claim 1 concerning measuring an amount of hydrogen peroxide generated by the redox reaction is supported for example by page 7, lines 15-17. The limitation in claim 6 concerning leaving the solution to stand at a temperature in the range from 20°C to 60°C for 6 to 120 hours is supported for example by page 7, lines 11-13. Claims 9, 11, 28 and 30 have been amended editorially. Claims 1-30 are pending. No new matter has been added.

Specification

The specification has been amended, taking the issues noted in the rejection into account. In particular, the reference WO 99/20039 has been removed. Applicants respectfully submit no new matter has been added into the specification.

Withdrawal of the rejection is respectfully requested.

Claim rejections - 35 U.S.C. § 112

Claims 1 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to claim the subject matter of the present invention. Claims 1 and 6 have been amended, taking the issues noted in the rejection into account. Applicants submit that claims 1 and 6 are definite.

Favorable reconsideration and withdrawal of the rejection are respectfully requested.

Claim rejections - 35 U.S.C. § 103

Claims 1-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP1 002874 A2 (Kömori et al.) in view of Biochemistry, 1988, Vol. 27, pp. 5470-5476 (Montellano et al.) and further in view of US Patent No. 6,127,138 (Ishimaru et al.). Applicants respectfully traverse this rejection.

Claim 1 requires the initial step of pretreating a sample with a fructosyl amino acid oxidase (FAOD) that acts on glycated amino acid other than glycated protein. In this way, glycated amino acid can be removed from the sample. Claim 1 then uses an FAOD that acts on the glycated protein so as to cause a redox reaction in the presence of a tetrazolium compound and sodium azide. These steps ensure that the resulting product of the redox reaction is generated not from the glycated amino acid, but only from the glycated protein. As a result, unwanted influence from glycated amino acid formed from exogenous substances

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administered via an intravenous drip or the like can be eliminated, thereby improving the accuracy in the measurement of the glycated protein (page 2, line 34 to page 3, line 22).

Komori is directed to a method of measuring glycated proteins in a sample using a redox reaction. Although Komori teaches using an FAOD to form hydrogen peroxide, nothing in the reference teaches or suggests removing the glycated amino acid with an FAOD before conducting the redox reaction, and thereby eliminating the influence of the glycated amino acid. In fact, Komori notes that the analyte to be measured may be, for example, a component in glycated amino acid, thereby teaching away from claim 1 (paragraph [0029]). Therefore, claim 1 is patentable over Komori.

Neither Montellano nor Ishimaru cures the deficiencies of Komori. Although Montello discloses the use of sodium azide and Ishimaru discloses the use of a general-purpose examining apparatus, the references fail to teach or suggest improving the accuracy of the measurement of glycated protein by removing the glycated amino acid with an FAOD before conducting the redox reaction. Therefore, claim 1 is patentable over the references, taken together or separately.

Claims 2-8 further limit and depend from claim 1. Therefore, claims 2-8 are patentable over the references for at least the same reasons as claim 1.

As to claim 9, the references fail to teach or suggest a measuring kit having a pretreatment reagent containing a first FAOD for the pretreatment of the sample, and a color-developing reagent containing a second FAOD for the color-developing reaction. Therefore, claim 9 and the dependent claims therefrom are patentable over the references, taken together or separately.

Favorable reconsideration and withdrawal of the rejection are respectfully requested.

Double Patenting

Claims 1-30 are rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1-22 of US Patent No. 6,790,665 (Yonehara).

Claims 1-22 of Yonehara recite a method of determining total hemoglobin. However, the claims fail to recite step of pretreating a sample with an FAOD that acts on glycated amino acid other than glycated protein. Therefore, claim 1 and the dependent claims therefrom of the present application are patentable over Yonehara. Furthermore, Yonehara fails to recite a measuring kit having a pretreatment reagent containing a first FAOD for the

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pretreatment of the sample, and a color-developing reagent containing a second FAOD for the color-developing reaction. Therefore, claim 9 and the dependent claims therefrom of the present application are patentable over Yonehara.

Favorable reconsideration and withdrawal of the rejection are respectfully requested.

In view of the above, favorable reconsideration in the form of a notice of allowance is requested. Any questions or concerns regarding this communication can be directed to the attorney-of-record, Douglas P. Mueller, Reg. No. 30,300, at (612) 455.3804.

Respectfully Submitted,

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